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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

ROMEO, DAVID S

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1647

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/592,685

Applicant(s)

BONADIO ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40,43-46,52-64,69,70,72,74-76 and 78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40,43-46,52-64,69,70,72,74-76 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 1. 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed March 4, 2002 (Paper No. 9) has been entered. Claims 40, 43-46, 52-64, 69, 70, 72, 74-76, 78 are pending.

5 The amendment filed June 12, 2000 (Paper No. 6) has been entered in part. The amendment to page 21, beginning at line 24, has not been entered because the text "FIG. 9." does not occur at the indicated position in the specification. The amendment to page 75, line 11, has not been entered because the text "FIG. 9." does not occur at the indicated position in the specification.

10 Applicant's election without traverse of unified group II in Paper No. 9 is acknowledged.

 Claims 40, 43-46, 52-64, 69, 70, 72, 74-76, 78 are being examined to the extent that they read upon a method binding TGF- β with a polypeptide comprising the amino acid sequence of
15 SEQ ID NO: 4.

 The disclosure is objected to because of the following informalities:

 A brief description of Figure 7, which shows a schematic representations of clones, is missing.

20 A brief description of Figure 8, which contains photographs, is missing.

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Figures 7 (nucleotide sequence), 9, and 10 are presented on separate panels. Applicant is reminded that once the figure is changed to meet the labeling requirement, the Brief Description of the Drawings and the rest of the specification must be amended accordingly.

Appropriate correction is required.

5

The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. The amino acid sequence in figure 8 does not recite the appropriate sequence identifier. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance. Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Applicant may bring the figure(s) into compliance by amending either the figure(s) or the "Brief Description of the Drawings" to recite the appropriate sequence identifier.

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Correction is required.

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Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

5 The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994). Support for the presently claimed invention cannot be found in the
10 08/479,722 parent application and the lack of such support raises the issue of new matter, and, hence, a failure to comply with the requirements of the first paragraph of 35 U.S.C. 112.

Claim Rejections - 35 USC § 112

15 The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25 Claims 40, 43-46, 52-64, 69, 70, 72, 74-76, 78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a

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way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to or encompass a method of binding TGF- β in vivo or in vitro by contacting the TGF- β with LTBP-3 and the attendant sequelae thereof. The claims require contacting an exogenous source of LTBP-3 with the TGF-

5 β . However, Saharinen (u10) discloses that the association of TGF- β 1-LAP with LTBP-1 is thought to occur only inside the cells (page 249, right column, full paragraph 1). Yin (v10) discloses that the LTBP-3 gene is co-expressed with TGF- β (Abstract). LTBP is linked by a disulfide bond to LAP (page 10147, right column, first full paragraph). LTBP-1, LTBP-2, and LTBP-3 may contribute to the regulation of extracellular matrix production by facilitating the

10 assembly and secretion of large latent growth factor complexes and then targeting the complex to specific connective tissues (last sentence of article) (emphasis added). Saharinen (w10) discloses that the major fraction (>90%) of secreted LTBPs does not contain TGF- β (page 101, left column, penultimate sentence) indicating that free LTBP does not bind TGF- β . The present specification lacks guidance for, and working examples of, binding TGF- β with LTBP-3 in the

15 absence of co-expression of TGF- β and LTBP-3. There is nothing in the prior art of record teaching the skilled artisan how to bind TGF- β with an exogenous source of LTBP-3. For the specification to enable the skill artisan to make and/or use the claimed methods it is incumbent upon applicant to provide teachings not present or not well established in the art, which the present specification has not done, otherwise the claims are an invitation to extensive, random,

20 trial and error experimentation. The terms "regulates" and "modulates" encompass both increases and decreases in activity or activation and the specification lacks guidance for, and working examples of, simultaneously or individually achieving either in the absence of co-

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expression of TGF- β and LTBP-3. The claims are viewed as encompassing the direct binding of LTBP-3 to mature, active TGF- β . However, TGF- β 1-BP (LTBP-1) does not bind directly to active TGF- β 1. See Kanzaki (x10), page 1051, right column, full paragraph 2. The specification lacks guidance for, and working examples of, the direct binding of LTBP-3 to mature, active

5 TGF- β . In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

10 The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52-54 are indefinite over the recitation of the terms "regulates" or "modulates" because the terms encompass both increases and decreases in activity or activation and it is

15 unclear which is intended. The metes and bounds are not clearly set forth.

Conclusion

No claims are allowable. The claims are free of the prior art of record.

20 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

25 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306

AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

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CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
AUGUST 11, 2002